

**RFTOP# 108 TITLE: Microbicide/Contraceptive Portfolio
Coordination System (MCPCS)**

Part I Request for Task Order (TO) Proposal

A. POINT OF CONTACT

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Contracts Management Branch
6100 Executive Blvd., Suite 7A07
Rockville, Maryland 20852
Attn: Jan L. Leahey

B. PROPOSED PERIOD OF PERFORMANCE

The Government anticipates awarding a forty-eight (48) month multi-year contract.

C. PRICING METHOD

The Government anticipates awarding a Not to Exceed Level of Effort Task

D. PROPOSAL INSTRUCTIONS

1. GENERAL INSTRUCTIONS

The following instructions establish the acceptable minimum requirements for the formatting and content of technical and business proposals, which are being submitted in response to this RFTOP.

The proposal shall be prepared and submitted in two volumes: Volume I - Technical Proposal and Volume II - Business Proposal. Each of these volumes shall be separate and complete, in and of themselves, so that evaluation of one may be accomplished independently of evaluation of the other. The Offeror shall submit information relating to "past performance" as a separate section of their business proposal. The Government will evaluate proposals in accordance with the evaluation criteria set forth in **Section G, "Evaluation Factors" page 7**. It is essential that Offerors address all elements of the evaluation criteria.

The RFTOP does not commit the Government to pay any costs for preparation and submission of a proposal. In addition, the Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with this proposed acquisition.

The proposal shall be signed by an official authorized to bind the Offeror's organization to perform if a task order is awarded in response to this RFTOP.

2. VOLUME I - TECHNICAL PROPOSAL

The staff hours proposed for individuals should be allocated against each task or subtask required for this project. (This information may be presented in a spreadsheet format).

a) TECHNICAL APPROACH

The technical proposal must discuss the proposed technical approach in sufficient detail to clearly and concisely demonstrate the Offeror's understanding of the project's intent and requirements as specified in the Statement of Work.

The technical proposal shall fully describe the technical and administrative aspects of accomplishing each task and include discussion of the Offeror's familiarity with work which includes:

- 1) A plan for the ongoing identification of prospective products and construction of an interactive database.
 - a) A contractor-generated computer security plan that will describe all the particulars and include a fully documented, demonstrable computer security program. The plan will be evaluated by the PO and the CO for appropriateness, effectiveness and cost-worthiness.
 - b) The Contractor shall clarify their understanding of all policies and procedures for safeguarding the information contained in Privacy Act systems of records, and confidential or privileged information.
- 2) Sample recommendations and milestones for guiding a potential Microbicide/Contraceptive product through drug development to licensure based on current Food and Drug Administration guidelines.
- 3) Information that demonstrates offeror's ability to collect and analyze drug development data, to include management of a statistical analysis database system.
- 4) Information that demonstrates offeror's ability to provide administrative support, including the ability to coordinate meetings, conference calls, and to provide assistance in publications/presentations.
- 5) Information that demonstrates offeror's ability to implement quality control measures that will ensure accurate, well-written, error-free deliverables and confidentiality of data obtained under the contract.

b) PERSONNEL QUALIFICATIONS/MANAGEMENT PLAN

The proposal shall include a management plan that specifies the personnel proposed to complete this project along with their proposed duties and the amount of time they will be

assigned to this requirement. The plan shall discuss roles and commitments of staff proposed as key persons, in addition to including an organizational chart that outlines how the project will be managed. Include resumes of all key staff and provide information relating to education, background, recent experience, and expertise relevant to the specific requirements of this RFTOP.¹

The technical proposal must include a list of names and proposed duties of the professional personnel, consultants, and key subcontractor employees assigned to the project. The Technical Proposal shall not include PRICE; however, proposed staff hours should be allocated against each task or subtask for the project. (This information may be presented in a spreadsheet format).

The Government has included the following labor categories as recommendations only and will consider alternative staffing approaches that best accomplishes this work.

1. Principal Investigator (key personnel):

Shall possess experience in product development and ability to assess Microbicide/Contraceptive products. Evidence of past ability to hire staff for projects in a way that reflects flexibility and responsiveness to changing needs. Evidence of ability to work with industry/academia in a confidential and service-oriented manner.

2. Project Manager (key personnel):

The Project Manager (PM) shall serve as the principal point of contact with the Government and will be responsible for: 1) providing direct supervision and coordination of project staff and consultants; 2) providing, assuring and monitoring the quality control of assignments/tasks; 3) providing staffing continuity; 4) monitoring contract progress; 5) providing deliverables; 6) preparing reports; and 7) maintaining budget control. In some case the PI and PM may be the same person.

¹ Evidence of lack of potential conflict of interest due to financial holdings in a microbicidal development company.

3. Other Personnel/staffing plan:

Relevance and extent of experience of other professional and research technical and support staff in the area of product development and Microbicide/Contraceptive s. (e.g. development of drug development milestones, knowledge of and ability to evaluate the pre-clinical and clinical development process including FDA guidelines, and in statistical modeling and database system management.) The logistical adequacy of the staffing plan for the conduct of the project, including the time commitment of the professional and technical staff.

c) **CORPORATE EXPERTISE**

For the purposes of this task, NICHD is seeking organizations possessing expertise in the following areas:

- product development and Microbicide/Contraceptive s,
- knowledge of and ability to evaluate the pre-clinical and clinical development process including FDA guidelines;
- database system management,
- scientific report writing, editing;
- quantitative and qualitative analysis;
- preparing proceedings of scientific meetings, conferences and workshops; preparing technical manuals;
- planning and conducting meetings, conferences and workshops

d) **FACILITIES AND RESOURCES**

Documentation demonstrating availability of adequate facilities, equipment, and resources necessary to conduct this project.

3. VOLUME II - BUSINESS PROPOSAL

The Contractor shall furnish a complete unit and estimated breakdown for labor for each year of this Task Order: state the estimated number of hours; provide a detailed explanation of the labor categories and the estimated number of hours for each category, which corresponds to each task/subtask as shown in the Statement of Work. Additionally, the business proposal shall include material costs, subcontracting costs, travel, subscription services, etc, as applicable.² Other Direct Costs (ODCs) should be broken out and listed as a separate line item for each year of the Task.

Price will not be numerically scored; however, the Government will perform a price analysis utilizing price analysis techniques and procedures.

² The Government anticipates that \$10,000 will be allotted for ODCs for each contract year.

4. PAST PERFORMANCE

The Government will consider the Offeror's prior experience/past performance in managing projects similar to the requirements contained in this RFTOP. The Offeror shall submit the following information as a separate section of their business proposal:

A minimum of three (3) contracts and/or delivery orders completed during the last two (2) years under which the Offeror has performed tasks most similar to the work required in this Statement of Work. The Offeror shall supply verifiable referenced detailing their performance in similar contract/tasks with either State or Federal Government agencies, non-profit, or educational institutions. For each reference, the Offeror shall provide the following information:

Name of the Contracting Organization;
Contract/Delivery/Task Order Number;
Contract Type;
Total Contract Value;
Contracting Officer's Name, Telephone Number and Facsimile Number;
Project Officer's Name, Telephone Number and Facsimile Number; and
Explanation/Comments Regarding Problems Encountered and Corrective Actions Taken.

It is the responsibility of the Offeror to ensure that all information supplied as references is current and accurate. The Contracting Officer will not contact the Offerors if the information provided for references is incorrect, incomplete, or no longer current. Proposals which do not contain all of the required past performance information may be adversely affected in the evaluation of their past performance.

Each Offer will be evaluated on its performance under existing and prior contracts/task/delivery orders, which are similar in nature to the requirements of this RFTOP. The Government is not required to contact all references provided by the Offeror. Also, references other than those identified by the Offeror may be contacted by the Government to obtain additional information that will be used in the evaluation of the Offeror's past performance.

E. RESPONSE DUE DATE:

Questions relating to this requirement should be directed to Ms. Leahey's attention, via email, no later than (4:30p.m.) on business day three (3) after the posting date of this RFTOP. All relevant questions & answers will be forwarded to all prospective offerors.

Attn: Jan L. Leahey
EMAIL: leaheyj@mail.nih.gov
PHONE: 301.435.8867

One (1) original and three (3) hard copies of both the technical and business proposal must be submitted to Ms. Leahey's attention by 12:00 pm., on Nov 25, 2002. Proposals should be submitted to the following address:

NIH/National Institute of Child Health
And Human Development
Contract Management Branch,

6100 Executive Blvd., Suite 7A07
Rockville, Maryland 20852.
Attn: Jan L. Leahey

Concurrent with hard copy delivery, one (1) electronic version of your proposal should also be provided to Ms. Leahey's attention at the aforementioned email address.

F. TASK DESCRIPTION

The National Institute of Child Health and Human Development (NICHD) is seeking a contractor capable of establishing and maintaining a MICROBICIDE/ CONTRACEPTIVE PORTFOLIO COORDINATION SYSTEM (MCPCS). The overall goal of the MCPCS will be to expedite the licensure of 1-3 products for contraceptive/microbicide efficacy, in addition to providing administrative tasks in support of the system, which may include database system management, scientific report writing, editing; quantitative and qualitative analysis; preparing proceedings of scientific meetings, arranging conferences and workshops and preparing technical manuals.

STATEMENT OF WORK **Microbicide/Contraceptive Portfolio Coordination System (MCPCS)**

I. INTRODUCTION

The National Institute of Child Health and Human Development (NICHD) is seeking a contractor capable of establishing and maintaining a MICROBICIDE/CONTRACEPTIVE PORTFOLIO COORDINATION SYSTEM (MCPCS) for the Contraception and Reproductive Health Branch (CRHB). The overall goal of the MCPCS will be to expedite the licensure of 1-3 products for contraceptive/microbicide efficacy. For the purposes of this requirement, microbicides/ contraceptives are defined as the chemical products that prevent the spread of sexually transmitted infections (STIs), including human immunodeficiency virus (HIV), and potentially could act as contraceptives.

NICHD is seeking a contractor possessing extensive experience and expertise in the field of microbicides/contraceptives. In performing this task, the contractor at a minimum shall: 1) identify prospective products that should undergo further development; 2) conduct analyses of the potential for further development of the prospective products, which may include data collection, literature searches, statistical analyses, etc.; 3) provide recommendations for developmental plans, including specific milestones, for the products identified in item #1; 4) provide recommendations for possible changes in the developmental plans, based on results of the analyses described in item #2; 5) coordinate meetings between Government, industry and academia involved in microbicide/spermicide development; and 6) track government regulations required for microbicide /spermicide product licensure.

In evaluating this RFTOP, the Government is seeking evidence that demonstrates the Offeror's prior experience in developing licensed products from pre-clinical stages to market.

II. BACKGROUND

In July 1999, the CRHB convened a panel of experts to advise the staff on issues related to the programmatic activities undertaken within the CRHB. Recommendations coming forth from that review were presented to NICHD Advisory Council in September by the chair of the review group. A theme to come out of the committee's recommendations was a need to develop a means

of identifying “important compounds that could ultimately be brought to the stage of technology transfer.” Specifically, the fifth recommendation of the group was as follows: *“A scientific advisory committee, which is independent of the membership of the Branch and its contractors should be formed to provide advice on the direction of research, to assist in development of pharmaceuticals, and to assist in identification of the appropriate compounds for further testing. Such a group could also assist in the medium and long range strategic planning of this section.”*

CRHB’s microbicide/contraceptive research program consists of identifying and developing new active agents for use in spermicide/microbicides. These activities include: 1) screening of candidate compounds for spermicidal and antiviral (HIV) activity, 2) biochemical modification of compounds for optimal dual activity, 3) assessing vaginal irritation in animal models, 4) product formulation, and 5) clinical testing. CRHB maintains an open call, via periodic announcements in the Commerce Business Daily, for compounds with dual spermicidal and microbicidal activity. NICHD has screened more than 200 chemical entities for in vitro spermicidal activity (Sander Cramer assay) and anti-HIV activity (cell free and cell-associated assays or viral binding inhibition assay).

CRHB also maintains a grant portfolio in the area of microbicides/contraceptives submitted as ROIs or SBIRs. In 2001, NICHD and the National Institute of Allergy and Infectious Disease (NIAID) funded six pre-clinical Program Projects grants covering an additional 15-20 compounds/derivatives. Four additional projects are expected to be funded in 2002, and a reissuance of the pre-clinical funding in 2003 and 2004 is anticipated.

To date, the CRHB has sponsored four Phase I clinical trials in the Contraceptive Clinical Trials Network (CCTN), and has initiated a Phase II/III contraceptive study of BufferGel sponsored by Reprotect. Examples of companies (and products) the CRHB has worked with are: Biosyn (C31G or Saavy), ReProtect (Buffer Gel), Biotek (Foaming N-9 gel), Novavax (Novasomes), Procept (Pro2000), Magainin Pharmaceuticals (Magainins), Jelling (polybiguanides), and the NCI/NIAID (Benzoic acid,2,2=-dithiodi-,dihydrazide).

As the research in this area expands, the need to address recommendations of the July 1999 Advisory Group has become more acute. The main objective of this RFP is to solicit a microbicide/contraceptive portfolio management group to provide expertise and guidance in microbicide/contraceptive development, from basic drug discovery through pre-clinical and clinical development.

III. PURPOSE

1. The purpose of this task is to assemble a dedicated body of personnel able to track the increasing number of compounds in the area, provide analytical data as to the progress of those compounds, and give recommendations to the developers of those compounds to expedite drug development. During the performance of this multi-year task, the Government anticipates that specific services will be ongoing, but other services will vary with the needs of the field.
2. The initial and ongoing requirement of this task will be the compilation of all the compounds in the NICHD (NIH) portfolio that are under investigation as microbicides/contraceptives. Subsequently, the contractor will obtain information on microbicide/contraceptive products being developed outside the NIH. This compilation will

include the state of development of the compound i.e. pre-clinical safety, phase I clinical, etc., as well as other pertinent identifiers, such as company affiliation, which may be required by the Project Officer (PO). This compilation will take the form of an interactive database available to the contractor, PO, and specific personnel identified by the PO.

3. Subsequent to award of this task, the Government anticipates the initiation of one or more meetings with compound developers to explain the role of the contractor in the development process and to solicit input for the database.
4. As the task develops, the contractor will work with the PO to conduct analysis on specific products, develop milestones, and make recommendations regarding product development plans.

IV. SPECIFIC REQUIREMENTS

The contractor shall provide staffing who possess the requisite skills and expertise to support specific areas, which at a minimum will include the following tasks:

TASK 1. PRODUCT ASSESSMENT SUPPORT

A. Microbicides/Contraceptives Field Assessment

The contractor shall identify, to the extent feasible, all existing prospective products in development in the microbicide/contraceptive field. The following requirements shall be performed in support of this task:

1. The contractor shall meet with the PO during the first week subsequent to award of this task to clarify questions and to discuss milestones.
2. During the first month of the contract, the contractor shall develop methods and/or procedures to identify, access and collect data and information from a variety of primary, secondary or other sources of information.
 - a) The contractor shall clarify their plan for maintaining confidentiality of the data and will be required to prepare a separate Quality Assurance (QA) Plan (see Task 4).
- The Contractor is not expected to have access to primary data for all products. However, the Contractor is expected to have a plan to obtain data from other sources, to the extent available, which provides information of the product's development.
3. Within 6 months the Contractor shall develop a draft plan for developing a data base that includes the following:
 - a) The computerized database must be interactive and secure. Fields would include, but not be limited to, product name(s), sponsor name(s), contact
 - b) Person(s), description of product and mode of action (by class of compound), pre-clinical assays performed to date and results if available, clinical trials to date and results if available, regulatory documents filed, cost, and other special considerations.
 - c) The database should be searchable by any field, including stage of development and developmental problems.
 - d) The database should indicate the validity of the data for each field i.e. primary source, secondary source, etc.

B. Microbicides/Contraceptives Field Evaluation³

The Contractor shall provide support for a variety of analytic and evaluative tasks from the information contained in the database. Support will include the range of microbicide/contraceptive development from “de novo” design to implementation of full-scale program evaluations, including assistance with study design; information development, collection and compilation; methods development; analysis and evaluation.

1. Topics may include but not be limited to resources assessment, progress assessments of one or more compounds in development, comparative development plans and outcomes, delivery and distribution and plans for maximizing efficiency of product development.
2. The Contractor shall integrate these findings into existing documents or publish them as separate, stand alone reports and studies. The Contractor shall be able to perform these tasks in short-turn around (two to eight weeks) and long-term (up to two year) time frames.
3. Some analytic and evaluative tasks may or may not involve use of the database and other sources of information, including literature searches. The types of analysis and evaluations could include, but not be limited to the following: an evaluability assessment, a case-study, a meta-analysis, a cost-benefit study, an epidemiological study, a systems analysis, a bibliometric or citation analysis and/or an impact analysis.
4. The Contractor shall develop and apply evaluative techniques, including identifying and developing key measures and indicators to help assess program performance, costs, etc.
5. The Contractor shall perform statistical comparisons, to help examine, analyze and evaluate specific or complex program related to microbicide/spermicide development.
6. The Contractor shall assist with interpretation, synthesis, and preparation of analyses for presentation or publication.
7. The Contractor shall advise and suggest alternative modes for displaying information and/or data and shall be asked to prepare a variety of graphics for possible publication or use in documents or other studies and special reports.
8. All relevant reference files, developed under this contract, which may be located at the Contractor’s facility, are the exclusive property of the NICHD. The Contractor shall respect the confidentiality of this information and shall not use this information for any purpose other than to carry out the work of this contract.

³ For costing purposes assume tracking 20-30 compounds in the database and 6-8 analytic or evaluative tasks per year. Since the majority of analytic and evaluative tasks will occur after construction of the database, we do not anticipate but 1-2 requests during the first year. Similarly, initial construction of the database will take more resources during the first year than updating the database in subsequent years. Subsequently the contractor may receive 1-2 requests quarterly.

TASK 2. WRITING, EDITING AND PUBLISHING SUPPORT⁴

The Contractor may be required to write and edit a variety of materials including technical documents as well as lay documents, where it will be essential to translate scientific terminology into language the public can understand. This task requires expertise in the following:

1. Materials, on topics specified by the PO, to be written, edited and published include, but are not limited to: research reports and highlights, articles, annual reports, talking points, handbooks, brochures/pamphlets, bibliographies, fact sheets, technical publications, posters, copy for audiovisuals.
2. Support in the area of writing, editing and publication preparation will vary depending on the stage of the report and as required by the PO. Report writing and editing support may be limited to typing and editing of recorded, handwritten, or draft typed materials; condensing, synthesizing and rewriting existing reports, manuscripts, narratives to provide a final draft for the PO's review, and basic copy editing for correct grammar and clarity.
3. In some instances, the Contractor shall meet with scientific program staff or may be required to perform independent research to prepare original first drafts of each report.
4. These activities may also include advising and suggesting alternative modes to display information, coordinating the writing of portions by various contributors; distributing drafts; collating comments on drafts; providing revised drafts through several review cycles; typing the report in final form, duplicating a limited number of copies, and providing camera-ready copy to vendor(s) or the Government Printing Office (GPO) for publishing and printing.
5. Examples of research reports to be prepared include, but shall not be limited to, the following:
 - a) Summary of NIH Product Development Pipeline
 - b) Update of the NICHD Contraceptive Microbicide Research and Development Program booklet

TASK 3. LITERATURE SEARCHES

The Contractor shall perform topical scientific literature searches and retrieving pertinent information, such as abstracts and full texts as follows:

1. The Contractor may be requested to conduct literature surveillance on research topics in the area of microbicide/contraceptive development.

⁴ *Estimated annual writing, editing and publishing support requirements are:*

- a) *One to two (1-2) special reports, which will be, on average, 30 single spaced pages long. It is estimated that five (5) photocopies are required of each.*
- b) *One (1) brochure of 10 double-spaced pages. It is estimated that 500 copies would be printed of each.*

2. The Contractor may also be required to do special searches for Institute staff and have access to National Library of Medicine databases and other on-line sources of information.

TASK 4. QUALITY MANAGEMENT, MEETINGS AND PROGRESS REPORTS

- a) The contractor shall develop a quality assurance (QA) plan for overall task management and for operating the MCPCS. The QA plan shall be submitted to the PO within one (1) month of the effective date of task order award and shall be reviewed and updated at least annually. The QA plan shall include, but not be limited to:
 - General procedures to help ensure timeliness and accuracy
 - General communication guidelines
 - Specific deliverable formats & dates
 - Data security and confidentiality
 - Other issues discussed during the initial meeting
- b) Monthly progress reports shall be submitted no later than the 10th day of every month (unless modified during the initial meeting). Each report shall include the following:
 - information relating to activities completed under each task area during the previous calendar month
 - potential problems and proposed solutions
 - pending activities that are upcoming in the next three months
- c) Meetings shall be held with the PO as often as required, but not less than quarterly. During the first six months of year one, meetings may occur monthly. Meetings shall be held at the NICHD offices in Rockville, Maryland. The PO and Project Director shall communicate by telephone and email as needed.
- d) A final report shall be developed and submitted one month before the close of the contract. The report shall contain the following, at a minimum:
 - Summary of activities completed under each task for the length of the contract
 - A summary of achievements
 - A summary of issues that will be used as the basis for the final presentation.
- e) During the final month of the contract, the contractor and PO shall clarify plans for the final presentation, which will be presented to senior management at the NICHD offices in Rockville, Maryland.

TASK 5. CONTRACT CLOSEOUT

1. Within two (2) weeks after the end of the task order, the Contractor shall transfer all NICHD materials to the Government. Upon completion of the task order, the Contractor shall box, pack, or crate all NICHD materials for transfer as directed by the PO and CO.

2. The Contractor shall deliver the following:

- a) All reference files, working files, writers files, publications, and other materials used to respond to inquiries;
- b) All software programs developed or altered in the performance of this contract and for which contract funds were expended. These shall be provided in the form of duplicate copies of magnetic tapes, dumps of programs, and dumps of sample records. The Contractor shall also provide full documentation pertaining to the programs.
- c) All items listed in this section shall be packed in new boxes of uniform size, labeled with a unique number, and delivered along with copies of an inventory showing the contents of each box in accordance with the delivery schedule

V. OPTION ITEMS:

In addition to the types of services described above, this task will provide for separately priced⁵ **Option Items, which will require the following support:**

MEETING AND CONFERENCE SUPPORT

1. CONFERENCE SUPPORT

The Government anticipates the need to conduct one (1) large conference which will be held during the first year of the task in the DC Metro Area or New York area and include approximately 200 non-federal participants. The conference will be a two (2) day event. In arranging this conference the contractor shall provide for the following:

- a) Site selection and reservation.
- b) Travel arrangements
- c) Meeting room arrangements
- d) Preparation of pre-meeting materials
- e) Meeting support (not to include transcription)
- f) Post-conference support

2. WORKSHOP SUPPORT

The Government anticipates the need to hold approximately three (3) workshops on the NIH campus in Bethesda, Maryland each year of the task. These workshops will involve approximately thirty (30) non-federal participants. In conducting each workshop, the contractor shall provide:

- a) Site selection and reservation.
- b) Travel arrangements
- c) Meeting room arrangements
- d) Preparation of pre-meeting materials
- e) Meeting support (not to include transcription)
- f) Post-conference support

⁵ Offerors should price the conference and each workshop separately.

VI. DELIVERABLES

SCHEDULE OF DELIVERABLES

Item #	Item Description	# of Copies	Date of Delivery from Effective Date of Delivery Order
1.	Initial meeting		One week EDOC
2.	Prepare a draft work plan	2	Two weeks after meeting
3.	Prepare a final work plan	2	One month after meeting
4.	Quality Assurance Plan	2	W/in one month of task award
5.	Design and develop a database structure		W/in six months of task award
6.	Weekly conference calls	TBD	Quarterly
7.	Meetings		
8.	Monthly progress reports	2	10 th working day of each month
9.	Final presentation	1	To be conducted in Rockville, Maryland
10.	Annual Final report	2	30 days prior to anniversary date of end of task

ITEMS FOR DELIVERY

In addition to other terms of the contract, the Contractor shall submit Technical/Activity Progress Reports covering the work accomplished during each reporting period as stated below.

A. Monthly Progress Reports

The Contractor shall submit within 10 days following the end of each month copies of Monthly Progress Reports, which shall consist of:

1. A cover page containing:
 - a. Task Order number and title
 - b. Period of performance being reported
 - c. Contractor's name and address
 - d. Author(s)
 - e. Date of submission

2. An introduction, covering the purpose and scope of the contract effort.
3. Summaries, or computer printouts, of activities as specified in the Work Statement:
 - a) Product Database Report
 - b) Product development plans, milestones and recommendations by product.
 - c) Results of data collection, analyses and literature searches.
 - d) Changes in regulatory guidelines.
 - e) Market analysis, current technologies and resources, and other areas of work supported by the contract.
4. Summary of meeting/communication issues.
5. Summary of data management issues, to include problems and solutions related to computer hardware and software.
6. Summary of product-specific issues, to include difficulties and solutions related to obtaining information and/or interactions with product sponsors.
7. Summary of meetings/discussions with PO regarding issues relevant to the conduct of the contracted work.
8. Personnel Report, to include name, title, percent effort and responsibility of each individual that is working on the contract.

B. Annual/Final Reports

1. The Contractor shall submit copies of an Annual and Final Progress Report. The Final Report shall cover the entire contract performance period and be in sufficient detail to explain comprehensively the tasks accomplished.
2. Annual Reports shall be submitted 30 days prior to the anniversary date of the contract. The Final Report shall be submitted 30 days prior to the expiration date of the contract. An Annual Report is not required for the period when the Final Report is due.

C. Technical Report Distribution

Copies of the technical reports shall be submitted in both electronic formats to the: PO (TBD) and Contracting Office.

D. Invoice Submission

The Contractor shall submit an original and two (2) copies of its invoice to:
Contracts Management Branch,
6100 Executive Blvd., Suite 7A07
Rockville, Maryland 20852

The Contractor agrees to include the following minimum information on its invoice:

- Contractor's Name and Address;
- Task Order Number;
- Invoice Number;
- Description of Services (including the hours, labor category and specific task);
- Invoice Period;
- Payment terms; and
- Taxpayer Identification Number (TIN).

VII. DELIVERY ORDER ADMINISTRATION DATA

1. AUTHORITIES OF GOVERNMENT PERSONNEL

Notwithstanding the Contractor's responsibility for total management during the performance of this delivery order, the administration of the delivery order will require maximum coordination between the Government and the Contractor. The following individuals will be the Government's points of contact during the performance of this delivery order:

a) Contracting Officer

All administration shall be performed by Ms. Jan Leahey, Contracting Officer, NICHD, Contracts Management Branch, 6100 Executive Blvd., Suite 7A07, Rockville, Maryland 20852. All communications pertaining to contractual and/or administrative matters under this task should be addressed to Ms. Jan Leahey at the aforementioned address.

b) Project Officer

The Project Officer (PO) shall be designated on the authority of the Contracting Officer at the time of delivery order award to monitor all technical aspects of the contract. The type of actions within the purview of the Project Officer's authority are to assure that the Contractor performs the technical requirements of the task order and to notify both the Contractor and the Contracting Officer of any deficiencies observed. A letter of designation shall be issued to both the PO and the Contractor at the time of task order award setting forth in full the responsibilities and limitations of the PO.

2. TECHNICAL MONITORING

Performance of the work under this delivery order shall be subject to the technical monitoring of the PO. The term "Technical Monitoring" is defined to include, without limitation, the following:

- a) Technical directions to the Contractor that redirect the contract effort, shift work emphasis between work areas or assignments, require pursuit of certain lines of inquiry, fill in details or otherwise serve to accomplish contractual scope of work.
- b) Providing information to the Contractor for assistance in the interpretation of drawings, specifications or technical portions of the work description.
- c) Review and, where required by the task order, approval of technical reports, drawings, specifications and technical information to be delivered by the Contractor to the Government under the task order.

Technical direction must be within the general scope of the work stated in the task order. The Project Officer does not have the authority to, and may not issue, any technical direction which: (i) constitutes an assignment of additional work outside the general scope of the order; (ii) constitutes a change as defined in the task order clause entitled "Changes"; (iii) in any manner causes an increase in the total task order cost or the time required for delivery order performance; or (iv) changes any of the expressed terms, conditions, or specifications of the task order.

All technical directions shall be issued in writing by the Project Officer or shall be confirmed by him/her in writing within five (5) working days after issuance.

The Contractor shall proceed promptly with the performance of technical directions duly issued by the Project Officer in the manner prescribed within his authority under this provision.

If, in the opinion of the Contractor, any instruction or direction issued by the Project Officer is within one of the categories as defined in (i) through (iv) above, the Contractor shall not proceed, but shall notify the Contracting Officer in writing within five (5) working days after the receipt of any such instruction or direction and shall request the Contracting Officer to modify the delivery order accordingly. Upon receiving such notification from the Contractor, the Contracting Officer shall issue an appropriate delivery order modification or advise the Contractor in writing that, in his opinion, the technical direction is within the scope of this article and does not constitute a change under the Changes Clause of the task order. The Contractor shall thereupon proceed immediately with the direction given. A failure of the parties to agree upon the nature of the instruction or direction or upon the delivery order action to be taken with respect thereto shall be subject to the provisions of the delivery order clause entitled "Disputes."

3. KEY PERSONNEL

Key Personnel are those employees considered essential to the work being performed under this delivery order. Prior to removing, replacing, or diverting the specified individual, the Contractor shall notify the Contracting Officer reasonably in advance and shall submit justification (including proposed substitutions) in sufficient detail to permit evaluation of the impact on the task order. The Contractor without the written consent of the Contracting Officer shall make no diversion, provided that the Contracting Officer may ratify in writing changes made due to events beyond the control of the Contractor and such ratification shall constitute the consent of the Contracting Officer required by this clause.

Examples of events beyond the control of the Contractor are (1) prolonged sickness, (2) termination of employment, and (3) death. Key personnel, with the consent of the Contracting Officer, may be amended from time to time during the course of the delivery order to either add or delete personnel, as appropriate.

Name

Title

TBD

TBD

VIII. Price and Option Items

1. The Government shall not be obligated to reimburse the Contractor for amounts incurred in excess of the contract amount, and the contractor shall not be obligated to continue performance under the contract or otherwise incur amounts in excess of the contract unless and until written notification is received by the contractor from the contracting officer which sets forth a revision of the contract amount. No notice, communication, or representation in any other form, or from any person other than the contracting officer shall affect the amount of this contract.
2. Total funds currently available for payment and allotted to this contract are \$ _____
3. It is estimated that the amount currently allotted will cover performance through _____.
4. The Contracting Officer may allot additional funds to the contract without concurrence of the contractor.
5. The amounts negotiated (and anticipated incremental funding schedule) for this contract are as follows:

Sample Pricing Table

ITEM	PRICE	CUMULATIVE PRICE
Year One		
Year Two		
Year Three		
Year Four		
Option Item 1 (Conference)		
Option Item 2 (Workshop 1)		
Etc....		

G. EVALUATION FACTORS

a. GENERAL

All aspects of the proposals are subject to discussions, including technical approach, price and contractual terms and conditions. However, the Government reserves the right to make an award without discussions. Therefore, it is important that your proposal be submitted initially on the most favorable terms from both the technical and price standpoint. Proposals submitted in response to this RFTOP will be evaluated in accordance with the evaluation criteria stated below:

1. TECHNICAL APPROACH (40 points)

Offerors proposals shall be evaluated on the following:

- Demonstrated full and complete understanding of the objectives of the Statement of work.
- An understanding of maintaining data security and information relating to the Privacy Act.

2. PERSONNEL QUALIFICATIONS/MANAGEMENT PLAN (30 points)

Offerors shall demonstrate the following:

- An effective and realistic management plan, which ensures timely, high-quality, cost-effective performance
- Availability, amount and relevance of management experience of the proposed key staff in managing contracts of similar size and scope to this task. Present evidence that demonstrates capability to manage multitask projects with results that are credible, of high quality, timely, and within budget;
- Qualifications (experience, expertise and educational background) of personnel relative to the requirements of individuals task areas;

3. CORPORATE EXPERTISE (25 points)

Offerors shall demonstrate the following:

- Ccorporate experience in planning and managing projects in areas comparable to those outlined in the Statement of Work.
- Corporate experience in fulfilling the technical requirements of contracts of similar size and scope to that specified in this solicitation.

4. FACILITIES AND RESOURCES (5 points)

- Offeror possesses adequate facilities and equipment to conduct this work.

TOTAL

100 points

b. PRICE EVALUATION

Price will not be numerically scored. The Government will perform a price analysis utilizing price analysis techniques and procedures.

c. PAST PERFORMANCE

An evaluation of Offeror's past performance information will be conducted subsequent to the technical evaluation. However, this evaluation will not be conducted on any Offeror whose proposal would not be considered further based on the results of the evaluation of factors other than past performance.

The evaluation will be based on information obtained from references provided by the Offeror, other relevant past performance information obtained from other sources known to the Government, and any information supplied by the Offeror concerning problems encountered on the identified contracts and corrective action taken.

The Government will assess the relative risks associated with each Offeror. Performance risks are those associated with an Offeror's likelihood of success in performing the acquisition requirements as indicated by that Offeror's record of past performance.

The assessment of performance risk is not intended to be the product of a mechanical or mathematical analysis of an Offeror's performance on a list of contracts but rather the product of subjective judgment by the Government after it considers all available and relevant information. When assessing performance risks, the Government will focus on the past performance of the Offeror as it relates to all acquisition requirements, such as the Offeror's record of performing according to specifications, including standards of good workmanship; the Offeror's record of controlling and forecasting costs; the Offeror's adherence to contract schedules, including the administrative aspects of performance; the Offeror's reputation for reasonable and cooperative behavior and commitment to customer satisfaction; and generally, the Offeror's business-like concern for the interest of the customer.

The Government will consider the currency and relevance of the information, source of the information, context of the data, and general trends in the Offeror's performance.

The lack of a relevant performance record may result in an unknown performance risk assessment, which will neither be used to the advantage nor disadvantage of the Offeror.

The following rating method shall be used in the evaluation of past performance information:

+2 Excellent - Based on the Offeror's performance record, no doubt exists that the Offeror will successfully perform the required effort. Sources of information are consistently firm in stating that the Offeror's performance was superior and that they would unhesitatingly do business with the Offeror again.

+1 Good - Based on the Offeror's performance record, little doubt exists that the Offeror will successfully perform the required effort. Sources of information state that the Offeror's performance was good, better than average, etc., and that they would do business with the Offeror again.

0 None - No past performance history identifiable.

-1 Marginal - Based on the Offeror's performance record, some doubt exists that the Offeror will successfully perform the required effort. Sources of information make unfavorable reports about the Offeror's performance and express concern about doing business with the Offeror again.

-2 Poor - Based on the Offeror's performance record, serious doubt exists that the Offeror will successfully perform the required effort. Sources of information consistently stated that the Offeror's performance was entirely unsatisfactory and that they would not do business with the Offeror again.

d. AWARD

Offerors are advised that technical merit, staffing and past performance, are considered to be more important than price.

Award will be made to the Offeror whose proposal offers the best overall value to the Government with technical merit and past performance weighed more heavily than price. In the event that two (2) offerors are determined to be technically equivalent, price and past performance will be more strongly weighed in making a final award selection.

Task Order # NICS-108

TITLE: Microbicide/Contraceptive Portfolio Coordination System
(MCPCS)PART II-CONTRACTOR'S REPLY: CONTRACT #263-01-D-0

Contractor:

Address:

Points of Contact:

Phone:

Fax:

TOTAL ESTIMATED COST: \$
Reimbursement

Pricing Method: Cost-

PROPOSED COMPLETION DATE:

FOR THE CONTRACTOR: _____
Signature Date

=====

SOURCE SELECTION:

WE HAVE REVIEWED ALL SUBMITTED PROPOSALS AND HAVE
DETERMINED THIS FIRM SUBMITTED THE BEST OVERALL PROPOSAL AND
THE PRICE/COST IS REASONABLE:

Billing Reference # _____

Appropriations Data: _____

RECOMMENDED:

FAX # _____
Signature-Project Officer Date

APPROVED: _____

FAX # _____
Signature-Contracting Officer Date_____
NIH APPROVAL--CONTRACTOR SHALL NOT EXCEED THE ESTIMATED TASK ORDER AMOUNT
WITHOUT THE WRITTEN APPROVAL OF THE CONTRACTING OFFICER AND
ICS COORDINATORAPPROVED: _____
Anthony M. Revenis, J.D., NIH PICS Coordinator Date